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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

RUTH LARA, individually and as guardian of  
her minor child J.S., on behalf of themselves  
and those similarly situated,

Plaintiffs,

v.

PUFF BAR, NICK MINAS, PATRICK  
BELTRAN, COOL CLOUDS  
DISTRIBUTION, INC., UMAIS  
ABUBAKER and SHAHID SHAIKH,

Defendants.

Case No. 2:20-cv-08030-SDW-LDW

**DEFENDANTS PUFF BAR, NICK MINAS AND DEFENDANT PATRICK BELTRAN'S  
ANSWER AND AFFIRMATIVE DEFENSES TO SECOND AMENDED COMPLAINT**

Defendants Puff Bar, Nick Minas (“Minas”), and Patrick Beltran (“Beltran”) (collectively, “Defendants”), by and through their undersigned counsel, for their answer to Plaintiffs’ Second Amended Complaint, state as follows:

1. Paragraph 1 contains no allegations to which a response is required. To the extent that a response may be deemed to be required, Defendants admit that Plaintiffs purport to bring an action against them on behalf of themselves and others similarly situated.

### **INTRODUCTION**

2. Defendants deny the allegations in Paragraph 2.

3. Paragraph 3 states a legal conclusion to which no response is required. To the extent that a response may be deemed to be required, Defendants state that the subject FDA guidance document speaks for itself.

4. Defendants state that they lack knowledge or information sufficient to form a belief about the truth of the allegations regarding the marketing of any purported “Puff Krush” product, and so deny the allegations of Paragraph 4 relating to that product. Defendants admit that Puff Bar products are user-friendly. Defendants deny the remaining allegations in Paragraph 4.

5. Defendants deny the allegations in Paragraph 5.

6. Defendants deny the allegations in Paragraph 6.

### **PARTIES, JURISDICTION, AND VENUE**

7. Defendants state that they lack knowledge or information sufficient to form a belief about the truth of the allegations regarding the identities, age, citizenship of the Plaintiffs and so deny. Defendants deny that Plaintiff J.S. began using Puff Bar products “as a direct result of the numerous kid-friendly flavors offered by Puff Bar.” Defendants deny the remaining allegations in Paragraph 7.

8. Defendants state that they lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 8 and so deny.

9. Defendants state that they lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 9 and so deny.

10. Defendants state that they lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 10 and so deny.

11. Defendants deny the allegations in Paragraph 11.

12. Defendants admit that Puff Bar is a California corporation with a principal place of business in Glendale, California. Defendants admit that Puff Bar sold, marketed, and promoted Puff Bar disposable e-cigarettes and that it sold its products to citizens of the State of New Jersey. Defendants deny the remaining allegations in Paragraph 12.

13. Defendants admit that Defendant Minas is a citizen of California and is the Chief Executive Officer of Puff Bar. Defendants admit that, solely through Defendant Puff Bar, Defendant Minas was involved in marketing, promoting, and selling Puff Bar disposable e-cigarettes throughout the United States, including to citizens of the State of New Jersey. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegation that Defendant Minas is subject to the exercise of this Court's specific personal jurisdiction as to Plaintiffs' claims due to a lack of information regarding Plaintiffs' alleged sources of Puff Bar products and so deny. Defendants deny the remaining allegations in Paragraph 13.

14. Defendants admit that Defendant Beltran is a citizen of California and is the Chief Financial Officer of Puff Bar. Defendants admit that, solely through Defendant Puff Bar, Defendant Beltran was involved in marketing, promoting, and selling Puff Bar disposable e-

cigarettes throughout the United States, including to citizens of the State of New Jersey. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegation that Defendant Beltran is subject to the exercise of this Court's specific personal jurisdiction as to Plaintiffs' claims due to a lack of information regarding Plaintiffs' alleged sources of Puff Bar products and so deny. Defendants deny the remaining allegations in Paragraph 14.

15. Paragraph 15 contains allegations regarding another defendant to which no response is required.

16. Paragraph 16 contains allegations regarding another defendant to which no response is required.

17. Paragraph 17 contains allegations regarding another defendant to which no response is required.

18. Paragraph 18 states a legal conclusion to which no response is required. To the extent that a response may be deemed to be required, Defendants deny the allegations in Paragraph 18.

19. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 19 regarding the exercise of this Court's specific personal jurisdiction as to Plaintiffs' claims due to a lack of information regarding Plaintiffs' alleged sources of Puff Bar products and so deny.

20. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 20 regarding the exercise of this Court's specific personal jurisdiction as to Plaintiffs' claims due to a lack of information regarding Plaintiffs' alleged sources of Puff Bar products and so deny.

### **GENERAL FACTUAL ALLEGATIONS**

21. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 21 and so deny.

22. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 22 and so deny.

23. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 23 and so deny.

24. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 24 and so deny.

25. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 25 and so deny.

26. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 26 and so deny,

27. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 27 and so deny.

28. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28 and so deny.

29. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 29 and so deny.

30. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 30 and so deny.

31. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 31 and so deny.

32. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 32 and so deny.

33. Defendants admit that Puff Bar products are disposable e-cigarette devices that are self-integrated and feature an internal battery and chamber containing flavored e-liquid. Defendants admit that the battery is auto-activated and has a buttonless design, such that users need only start vaping to activate the device. Defendants also admit that the products have no removable parts, no pod to remove, and no charging port.

34. Defendants admit the allegations in Paragraph 34.

35. Defendants admit that Puff Bar is small enough to fit in a pocket and aerosolizes e-liquid to create a vapor. Defendants deny the remaining allegations in Paragraph 35.

36. Defendants admit that Puff Bar products use nicotine salts, with nicotine strengths of up to five percent (5%). Defendants deny the remaining allegations of Paragraph 36.

37. Defendants deny the allegations in Paragraph 37.

38. Defendants deny the allegations in Paragraph 38.

39. Defendants deny the allegations in Paragraph 39.

40. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 40 and so deny.

41. Defendants deny the allegations in Paragraph 41.

42. Defendants deny the allegations in Paragraph 42.

43. Defendants deny the allegations in Paragraph 43.

44. Defendants deny the allegations in Paragraph 44.

45. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 45 related to Puff Krush and so deny.

46. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 46 and so deny.

47. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 47 and so deny.

48. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 48 and so deny.

49. Defendants deny the allegations in Paragraph 49.

50. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 50 and so deny.

51. Paragraph 51 states a legal conclusion to which no response is required.

52. Defendants admit that, at one point in time, the quoted language appeared on Puff Bar's website and was subsequently removed. Defendants admit that Puff Bar had not obtained FDA approval to make a modified risk claim. Defendants deny the remaining allegations in Paragraph 52.

53. Defendants deny the allegations in Paragraph 53.

54. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 54 and so deny.

55. Paragraph 55 states a legal conclusion to which no response is required.

56. Paragraph 56 references a letter, the terms of which speak for itself.

57. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 57 and so deny.

58. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 58 and so deny.

59. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 59 and so deny.

60. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 60 and so deny.

61. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 61 and so deny.

62. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 62 and so deny.

63. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 63 and so deny.

64. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 64 and so deny.

65. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 65 and so deny.

66. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 66 and so deny.

67. Defendants deny the allegations in Paragraph 67.

68. Defendants deny the allegations in Paragraph 68.

69. Defendants deny the allegations in Paragraph 69.

70. Defendants deny the allegations in Paragraph 70.

71. Defendants deny the allegations in Paragraph 71.

72. Defendants deny the allegations in Paragraph 72.



73. Defendants admits that quoted language in Paragraph 73 appeared on Puff Bar's website at one point in time.

74. Defendants deny the allegations in Paragraph 74.

75. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 75 and so deny.

76. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 76 and so deny.

77. Defendants deny the allegations in Paragraph 77.

78. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 78 and so deny.

79. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 79 and so deny.

80. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 80 and so deny.

81. Defendants admit that nicotine is an addictive chemical. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 81 comparing nicotine to cocaine and heroin and so deny.

82. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 82 and so deny.

83. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 83 and so deny.

84. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 84 and so deny.

85. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 85 and so deny.

86. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 86 and so deny.

87. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 87 and so deny.

88. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 88 and so deny.

89. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 89 and so deny.

90. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 90 and so deny.

91. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 91 and so deny.

92. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 92 and so deny.

93. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 93 and so deny.

94. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 94 and so deny.

95. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 95 and so deny.

96. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 96 and so deny.

97. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 97 and so deny.

98. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 98 and so deny.

99. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 99 and so deny.

100. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 100 and so deny.

101. Defendants deny the allegations in Paragraph 101.

102. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 102 and so deny.

103. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 103 and so deny.

104. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 104 and so deny.

105. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 105 and so deny.

106. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 106 and so deny.

107. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 107 and so deny.

108. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 108 and so deny.

109. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 109 and so deny.

110. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 110 and so deny.

111. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 111 and so deny.

112. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 112 and so deny.

113. Defendants deny the allegations in Paragraph 113.

114. Defendants admit that the quoted statement appeared on Puff Bar's website at one point in time. Defendants deny the remaining allegations in Paragraph 114.

115. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 115 and so deny.

116. Defendants deny the allegations in Paragraph 116.

117. Defendants deny the allegations in Paragraph 117.

118. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 118 and so deny.

119. Paragraph 119 contains no allegations to which a response is required. To the extent a response is deemed to be required, Defendants admit that Plaintiffs purport to assert a class action on behalf of the stated proposed classes.

120. Paragraph 120 contains no allegations to which a response is required.

121. Defendants deny the allegations in Paragraph 121.

122. Defendants deny the allegations in Paragraph 122.

123. Defendants deny the allegations in Paragraph 123.

124. Defendants deny the allegations in Paragraph 124.

125. Defendants deny the allegations in Paragraph 125.

126. Defendants deny the allegations in Paragraph 126.

127. Defendants deny the allegations in Paragraph 127.

128. Defendants incorporate by reference their responses to the allegations in Paragraphs 1 through 127, above, as if fully set forth herein.

129. Defendants admit only that they advertised, promoted, and sold the Puff Bar devices, which were intended for the inhalation of aerosolized nicotine. Defendants deny the remaining allegations in Paragraph 129.

130. Defendants deny the allegations in Paragraph 130.

131. Defendants deny the allegations in Paragraph 131.

132. Defendants state that Paragraph 132 states a legal conclusion to which no response is required.

133. Defendants state that Paragraph 133 states a legal conclusion to which no response is required.

134. Defendants deny the allegations in Paragraph 134.

135. Defendants deny the allegations in Paragraph 135.

136. Defendants deny the allegations in Paragraph 136.

137. Defendants deny the allegations in Paragraph 137.

138. Defendants deny the allegations in Paragraph 138.

139. Defendants deny the allegations in Paragraph 139.

140. Defendants deny the allegations in Paragraph 140.

141. Defendants deny the allegations in Paragraph 141.

142. Defendants deny the allegations in Paragraph 142.

143. Defendants deny the allegations in Paragraph 143.

144. Defendants deny the allegations in Paragraph 144.

145. Defendants deny the allegations in Paragraph 145.

146. Defendants deny the allegations in Paragraph 146.

147. Defendants deny the allegations in Paragraph 147.

148. Defendants state that Paragraph 148 states a legal conclusion to which no response is required.

149. Defendants deny the allegations in Paragraph 149.

150. Defendants deny the allegations in Paragraph 150.

151. Defendants deny the allegations in Paragraph 151.

152. Defendants deny the allegations in Paragraph 152.

153. Defendants deny the allegations in Paragraph 153.

154. Defendants deny the allegations in Paragraph 154.

155. Defendants deny the allegations in Paragraph 155.

156. Defendants deny the allegations in Paragraph 156.

157. Defendants deny the allegations in Paragraph 157.

158. Defendants deny the allegations in Paragraph 158.

159. Defendants incorporate by reference their responses to the allegations in Paragraphs 1 through 127, above, as if fully set forth herein.

160. Defendants admit that Puff Bar products were sold on eliquidstop.com at one point in time, but deny that Puff Bar products are any longer sold on the site.

161. Defendants deny the allegations in Paragraph 161.

162. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 162 and so deny.

163. Defendants state that Paragraph 163 states a legal conclusion to which no response is required.

164. Defendants state that Paragraph 164 states a legal conclusion to which no response is required.

165. Defendants state that Paragraph 165 states a legal conclusion to which no response is required.

Defendants deny all allegations not specifically admitted herein.

### **AFFIRMATIVE DEFENSES**

1. Plaintiffs' complaint fails to state a claim upon which relief can be granted.
2. Further factual discovery may establish that some or all of Defendants are not subject to the Court's exercise of personal jurisdiction.
3. Plaintiffs' Complaint is defective in that Plaintiffs have failed to join necessary or indispensable parties.
4. The claims asserted in the Complaint are barred, in whole or in part, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint.
5. The claims asserted in the Complaint are preempted by federal law, including (without limitation) the Federal Food, Drug and Cosmetic Act.

6. If Plaintiffs have sustained any injuries or damages, such were the result of intervening or superseding events, factors, occurrences or conditions, which were in no way caused by the Puff Bar products and for which Defendants are not liable.

7. Plaintiffs may not recover from Defendants because the methods, standards, or techniques of designing, manufacturing, and labeling of the products at issue complied with and were in conformity with the generally recognized state of the art and with the laws of New Jersey at the time the products were designed, manufactured, and labeled.

8. Plaintiffs may not recover from Defendants because they had no role in the design, manufacturing, or labeling of the products at issue.

9. Plaintiffs may not recover from Defendants because they had no role in the distribution or sale of the products used by Plaintiff J.S.

10. Plaintiffs' claims are barred, in whole or in part, by doctrines of laches, waiver, unclean hands, estoppel and/or ratification.

11. Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' own negligence and/or assumption of risk.

12. To the extent that Plaintiffs' claims relate to the Puff Bar's advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitution of the State of New Jersey or that of any other state whose laws may apply, such claims are barred. Plaintiff's claims are also barred in whole or in part by the *Noerr-Pennington* Doctrine.

13. Plaintiffs' claims are barred, in whole or in part, by Plaintiff's or Decedent's failure to mitigate any damages allegedly sustained.



14. Plaintiffs' injuries and damages, if any, are barred in whole or in part by the actions, omissions, and/or conduct of third parties over whom Puff Bar had no control or authority and, thus, any recovery should be reduced or barred by such parties' proportionate fault.

15. Plaintiffs' claims are barred, in whole or in part, by the alteration, modification, or misuse by Plaintiff or third parties of the products at issue.

16. Any claim by Plaintiffs for punitive or exemplary damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of New Jersey or that of any other state whose laws may apply. Any law, statute or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it fails to provide adequate advance notice as to what conduct will result in punitive damages; (3) unconstitutionally may permit recovery of punitive damages based on harms to third parties, out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) unconstitutionally may permit recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to Puff Bar; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages award; (7) lacks

constitutionally sufficient standards for appellate review of punitive damages awards; (8) would unconstitutionally impose a penalty, criminal in nature, without according Puff Bar the same procedural protections that are accorded to criminal defendants under the constitutions of the United States, Georgia, and any other state whose laws may apply; and (9) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996); *State Farm Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

17. Plaintiffs' alleged injuries and damages, if any, were caused by the acts or omissions of Plaintiffs, and/or by the fault of Plaintiffs, and thus any recovery might be reduced accordingly or eliminated altogether in accord with applicable statutes and common law, including the law of New Jersey and/or the law of any state whose law may apply.

18. Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs did not rely to their detriment upon any statement by Puff Bar in determining to use the products at issue.

19. Plaintiffs' claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by the FDA under the FDCA and the Family Smoking Prevention and Tobacco Control Act ("TCA").

20. To the extent Plaintiffs assert claims that depend solely on violations of federal law, such claims are barred and should be dismissed. *See Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

21. Defendants provided adequate and complete warnings for their products.

22. If it is determined that any Puff Bar product was substantially and materially changed in condition, misused or abused, or was used in any unintentional or unforeseeable manner, the claims against Puff Bar must be barred.

23. Plaintiffs' claims are barred because based on the state of scientific, industrial, and technical knowledge during the relevant time periods, Puff Bar products at issue were reasonably safe for their normal and foreseeable use at all relevant times, in light of existing reasonably available scientific, industrial, and technical knowledge.

23. Plaintiffs' claims are barred by the doctrine described in Section 4 of the Restatement (Third) of Torts: Products Liability because the product(s) at issue complied with applicable product safety statutes and administrative regulations.

24. The Complaint fails to state a claim on which relief can be granted as to costs and disbursements, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, unjust enrichment, disgorgement, restitution, or treble damages.

25. Defendants deny that they participated in any conspiracy or conduct designed or intended to deceive or misrepresent the qualities and characteristics of any of the products sold.

26. No act or omission of Defendants was intentional, fraudulent, malicious, reckless, in any way morally culpable, or made with conscious, malicious, or intentional disregard for the health and well-being of Plaintiffs.

27. Plaintiffs are barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by the Plaintiffs without substantially impairing the usefulness or intended purpose of the products.

28. Plaintiffs' claims are barred by the doctrine(s) contained in § 402A of the *Restatement (Second) of Torts*, comment k to § 402A of the *Restatement (Second) of Torts* and the *Restatement (Third) of Torts: Products Liability*.

29. Plaintiffs' claims are barred, in whole or in part, by the "sophisticated user" and "informed user" doctrines.

30. Plaintiffs' claims are barred, in whole or in part, by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States because defendant's products are comprehensively regulated by the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"), the TCA and regulations promulgated thereunder, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA and TCA, with the purposes and objectives of the FDCA, the TCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should or should not be used in the labeling accompanying the device.

31. Plaintiffs' claims are barred in whole or in part because the minor Plaintiff was not a reasonably foreseeable or intended user of the subject projects.

32. Plaintiffs' claims are barred in whole or in part because there was not a practical and technically feasible alternative design that would have prevented the alleged harm without substantially impairing the reasonably anticipated or intended function of the product.

33. Plaintiffs' claims are barred in whole or in part because the characteristics of the product were known to the ordinary consumer or user and the alleged harm was caused by an unsafe aspect of the product that is an inherent characteristic of the product that would be

recognized by the ordinary person who uses or consumes the product with the ordinary common knowledge common the class of persons for whom the product is intended.

34. Plaintiffs' claims are barred in whole or in part because the alleged harm was caused by an unavoidably unsafe aspect of the product and the product was accompanied by an adequate warning or instruction.

Dated: March 3, 2021

Respectfully Submitted,

THOMPSON HINE LLP

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*Attorneys for Defendants Nick Minas and Patrick Beltran*

**CERTIFICATE OF SERVICE**

I certify that on this date I caused Defendants Puff Bar, Nick Minas, and Defendant Patrick Beltran's Answer and Affirmative Defenses to Second Amended Complaint to be filed with the Clerk of Court for the United States District Court for the District of New Jersey by using the CM/ECF system and understand that electronic notice of the filing will automatically be sent all counsel of record.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

s/ Brian Steinwascher  
\_\_\_\_\_  
Brian Steinwascher

Dated: March 3, 2021